

## REMARKS

Claims 28-38, 55 and 56 are pending. Claims 28, 36-38 and 55 are amended herein to recite that the claimed compositions consist essentially of the recited proanthocyanidins. Basis for this amendment may be found throughout the specification as originally filed.

### **I. REJECTION OF CLAIMS 28-38 and 55-56 UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 28-38, 55 and 56 are rejected for alleged lack of written description. The Office Action alleges that there is no support for the limitation “the proanthocyanidin constitutes at least 70 % of an active component of the composition” in claims 28 and 55.

As amended herein, the instant claims no longer recite “the proanthocyanidin constitutes at least 70 % of an active component of the composition.” Therefore, it is respectfully submitted that this ground of rejection has been rendered moot.

### **II. REJECTION OF CLAIMS 28-38 and 55-56 UNDER 35 U.S.C. §103(a), OVER KUZNICKI *ET AL.***

Claims 28-38, 41 and 55-56 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Kuznicki *et al.* (U.S. Patent No. 5,681,569) because the cited reference allegedly teaches a composition containing green tea solids extracted from tea material. The Office Action states that the extract contains 0.01-0.35% flavanols and catechins, wherein the catechin or a mixture of two or more catechins are catechin, epicatechin, galocatechin, epigallocatechin gallate and epicatechin gallate, and a pharmaceutical carrier. The Office Action alleges that the green tea composition of Kuznicki *et al.* inherently contains proanthocyanidin oligomers having the instant formula I and II and/or procyanidins such as the dimers and trimers of catechin and epicatechin because catechins are allegedly known to encompass these compounds which are known to be isolated from green tea.

The Office Action further alleges that the inherency of the green tea composition is supported by the Hashimoto *et al.* The Office Action urges that Hashimoto *et al.* teaches that proanthocyanidins are isolated from oolong tea. It is alleged that oolong tea is a well known green tea. The Office Action alleges that the compounds identified by Hashimoto *et al.* in the green tea compositions are the instant compounds having formula I or II.

The Office Action further alleges that Morimoto *et al.* also teaches proanthocyanidin containing compositions wherein the proanthocyanidins can be degraded to catechins and epicatechins. This rejection is respectfully traversed.

## Discussion

Applicant notes that the claims have been amended herein to recite that the claimed compositions consist essentially of the recited proanthocyanidins. As the Examiner notes in the Final Office Action, Kuznicki et al. is directed to green tea solids extracted from tea material, which contain, *inter alia*, “flavanols or catechins wherein the catechin or a mixture of two or more the catechins are catechin, epicatechin, gallocatechin, epigallocatechin gallate and apicatechin gallate” (see, the Final Office Action, page 4, lines 2-4). Thus, as appreciated by the Examiner and as well known in the art, green tea extracts contain a complex mixture of active components. The pharmaceutical compositions claimed herein consist essentially of the recited proanthocyanidins.

As noted in MPEP §2111.03, the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention (*quoting In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976))(emphasis in original). As is well known in the art, and as recognized by the Examiner, the other components present in green tea extracts described above materially affect the basic and novel characteristics of the tea. In particular, it is well known in the art that such other components have therapeutic activity.

There is no teaching or suggestion in Kuznicki, et al., to alter the green tea extract taught therein to consist essentially of the proanthocyanidins of the instant claims. Nor is any such teaching within the scope of knowledge of those of skill in the art. Thus, the instant claims, which are directed to pharmaceutical compositions consisting essentially of the recited proanthocyanidins, are not obvious over the teachings of Kuznicki et al.

### **III. REJECTION OF CLAIMS 28, 31-38 and 55-56 UNDER 35 U.S.C. §103(a) OVER JP 10245342**

Claims 28, 31-38 and 55-56 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over JP 10245342 because the reference allegedly teaches a pharmaceutical composition for diminishing the toxicity in nerve cells caused by  $\beta$ -amyloid protein containing a catechin or two or more of catechin such as epigallocatechin gallate and epicatechin gallate prescribed in effective amounts for diminishing the toxicity of  $\beta$ -amyloid protein, and a pharmaceutical carrier. The Office Action alleges that the green tea composition disclosed in the cited reference inherently contains proanthocyanidins oligomers having formula I and II and/or procyanidins such as the dimers and trimers of catechin and epicatechin because catechins are allegedly known to encompass these compounds which are known to be isolated from green tea. The rejection is respectfully traversed.

### Discussion

As noted above, the instant claims have been amended herein to recite that the claimed compositions consist essentially of the recited proanthocyanidins. As the Examiner notes in the Final Office Action, JP 10245342 is directed to green tea compositions which contain, *inter alia*, “a catechin or two or more of catechin such as epigallocatechin gallate and epicatechin gallate” (see, the Final Office Action, page 7, lines 4-5). Thus, as appreciated by the Examiner and as well known in the art, green tea compositions contain a complex mixture of active components. The pharmaceutical compositions claimed herein consist essentially of the recited proanthocyanidins.

As noted in MPEP §2111.03, the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention (*quoting In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976))(emphasis in original). As is well known in the art, and as recognized by the Examiner, the other components present in green tea compositions described above materially affect the basic and novel characteristics of the tea. In particular, it is well known in the art that such other components have therapeutic activity.

There is no teaching or suggestion in JP 10245342 to alter the green tea compositions taught therein to consist essentially of the proanthocyanidins of the instant claims. Nor is any such teaching within the scope of knowledge of those of skill in the art. Thus, the instant claims, which are directed to pharmaceutical compositions consisting essentially of the recited proanthocyanidins, are not obvious over the teachings of JP 10245342.

### **IV. REJECTION OF CLAIMS 28, 31-38 and 55-56 UNDER 35 U.S.C. § 103(a) OVER HASHIMOTO *ET AL.***

Claims 28, 31-38 and 55-56 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Hashimoto *et al.* because Hashimoto *et al.* allegedly teaches a composition containing or inherently containing a catechin or two or more of catechins such as epigallocatechin and dimers or proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts and a pharmaceutical carrier. The Office Action urges that the oolong tea composition in Hashimoto *et al.* inherently comprises the instant compounds because these compounds are known to be isolated from oolong tea. The rejection is respectfully traversed.

### Discussion

As noted above, the instant claims have been amended herein to recite that the claimed compositions consist essentially of the recited proanthocyanidins. As the Examiner notes in the Final Office Action, Hashimoto *et al.* is directed to oolong tea compositions

which contain, *inter alia*, “a catechin or two or more of catechin such as epigallocatechin and dimers and proanthocyanidins (having the formula I and II herein) and/or procyanidins such as the dimers and trimers of catechin and epicatechin” (see, the Final Office Action, page 8, lines 11-14). Thus, as appreciated by the Examiner and as well known in the art, oolong tea compositions contain a complex mixture of active components. The pharmaceutical compositions claimed herein consist essentially of the recited proanthocyanidins.

As noted in MPEP §2111.03, the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention (*quoting In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976))(emphasis in original). As is well known in the art, and as recognized by the Examiner, the other components present in oolong tea compositions described above materially affect the basic and novel characteristics of the tea. In particular, it is well known in the art that such other components have therapeutic activity.

There is no teaching or suggestion in Hashimoto et al. to alter the oolong tea compositions taught therein to consist essentially of the proanthocyanidins of the instant claims. Nor is any such teaching within the scope of knowledge of those of skill in the art. Thus, the instant claims, which are directed to pharmaceutical compositions consisting essentially of the recited proanthocyanidins, are not obvious over the teachings of Hashimoto et al.

#### **V. REJECTION OF CLAIMS 28, 31-38 and 55-56 UNDER 35 U.S.C. §103(a), OVER MORIMOTO ET AL.**

Claims 28, 31-38 and 55-56 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Morimoto *et al.* because Morimoto *et al.* allegedly teaches a composition containing a catechin or two or more catechins such as epigallocatechin and dimers and procyanidins in effective amounts and in pharmaceutical carrier. The Final Office Action urges that the compounds identified by Morimoto *et al.* are allegedly the instant compounds of formula I and II. The rejection is respectfully traversed.

#### **Discussion**

As noted above, the instant claims have been amended herein to recite that the claimed compositions consist essentially of the recited proanthocyanidins. As the Examiner notes in the Final Office Action, Morimoto et al. is directed to compositions which contain, *inter alia*, “a catechin or two or more of catechin such as epigallocatechin and dimers and procyanidins (having the formula I and II herein) such as the dimers and trimers of catechin and epicatechin” (see, the Final Office Action, page 9, lines 16-18). Thus, as appreciated by

the Examiner and as well known in the art, the compositions of Morimoto et al. contain a complex mixture of active components. The pharmaceutical compositions claimed herein consist essentially of the recited proanthocyanidins.

As noted in MPEP §2111.03, the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention (*quoting In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976))(emphasis in original). As is well known in the art, and as recognized by the Examiner, the other components present in tea compositions described above materially affect the basic and novel characteristics of the tea. In particular, it is well known in the art that such other components have therapeutic activity.

There is no teaching or suggestion in Morimoto et al. to alter the compositions taught therein to consist essentially of the proanthocyanidins of the instant claims. Nor is any such teaching within the scope of knowledge of those of skill in the art. Thus, the instant claims, which are directed to pharmaceutical compositions consisting essentially of the recited proanthocyanidins, are not obvious over the teachings of Morimoto et al.

#### **VI. REJECTION OF CLAIMS 28, 31-38 and 55-56 UNDER 35 U.S.C. §103(a), OVER HATANO *ET AL.***

Claims 28, 31-38 and 55-56 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Hatano *et al.* because Hatano *et al.* allegedly teaches a composition for anti-HIV containing or inherently containing a catechin or two or more of catechins such as epigallocatechin and dimers of proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts and a pharmaceutical carrier. The Office Action urges that the compositions in the cited reference inherently contains the instant compounds because these compounds are known to be isolated from *Camellia japonica* plants. The rejection is respectfully traversed.

#### **Discussion**

As noted above, the instant claims have been amended herein to recite that the claimed compositions consist essentially of the recited proanthocyanidins. As the Examiner notes in the Final Office Action, Hatano et al. is directed to compositions which contain, *inter alia*, “a catechin or two or more of catechin such as epigallocatechin and dimers and proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin” (see, the Final Office Action, page 10, lines 15-17). Thus, as appreciated by the Examiner and as well known in the art, the compositions of Hatano et al. contain a complex mixture of active components. The

pharmaceutical compositions claimed herein consist essentially of the recited proanthocyanidins.

As noted in MPEP §2111.03, the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention (*quoting In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976))(emphasis in original). As is well known in the art, and as recognized by the Examiner, the other components present in Camellia japonica plant extracts described above materially affect the basic and novel characteristics of the tea. In particular, it is well known in the art that such other components have therapeutic activity.

There is no teaching or suggestion in Hatano et al. to alter the compositions taught therein to consist essentially of the proanthocyanidins of the instant claims. Nor is any such teaching within the scope of knowledge of those of skill in the art. Thus, the instant claims, which are directed to pharmaceutical compositions consisting essentially of the recited proanthocyanidins, are not obvious over the teachings of Hatano et al.

In light of the above amendments and remarks, the Applicant respectfully requests that the Examiner reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney if a telephone call could help resolve any remaining items.

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Respectfully submitted,



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